Patent dispute: Delhi High Court gives a boost to access to affordable medicines

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Abstract

The Delhi High Court has rejected the petition filed by Bayer Corporation seeking to stop the Drugs Controller of India (DCGI) from registering a generic version of a patented cancer drug. The case was filed in 2008 by Bayer to try and introduce "patent linkage", which involves linking the registration (marketing approval) of drugs with their patent status. If Bayer's plea for "patent linkage" had been accepted by the court, it would have undermined public health safeguards contained in India's patent legislation. This comment discusses the Bayer case in the context of efforts by multinational pharmaceutical companies to introduce barriers to generic competition, the only proven means of reducing the prices of medicines to make them affordable to those in need. Bayer has filed an appeal in the Supreme Court, indicating that it does not intend to give up.

India is home to a large pharmaceutical generic industry that in addition to meeting domestic needs also supplies the developing world. However, its domestic production of essential medicines is constantly under threat – both from intellectual property norms adopted in trade agreements and from patent disputes that are being brought against the government of India by multinational pharmaceutical companies.

In a positive development, the Division Bench of the Delhi High Court stopped the German pharmaceutical company Bayer Corporation's latest attempt to introduce new "patent policing measures" to prevent generic competition in India. By ruling against Bayer on February 9, 2010, the Delhi High Court refused to undermine legal safeguards in India's patent law that help ensure access to more affordable essential medicines for patients in India and other developing countries. However, the battle is by no means over. Bayer has filed an appeal against the decision in the Supreme Court (1).

Background

Generic competition is the only proven means of reducing the prices of medicines to more affordable levels. AIDS and cancer treatment are an important illustration of the benefits of encouraging generic production. Currently the majority of people living with HIV on treatment in low- and middle-income countries use generic antiretroviral drugs manufactured mostly from India (2). It was only with the arrival of generic anti-retrovirals produced by Indian companies on the market in 2001 that prices started to reduce significantly – from $10,439 to $350 per patient per year for first-line AIDS treatment.

The first fixed dose combination of stavudine/ lamivudine/ nevirapine was developed by Cipla and went on to become instrumental in rolling out antiretroviral therapy in Africa, Latin America and Asia and other developing countries including India. Today, it is available for as little as US$80 per patient per year – 1/130th of the price demanded by multinational pharmaceutical companies in 2001. With continued generic production, the price of improved first-line AIDS treatment (the three-in-one fixed-dose combination of tenofovir/ lamivudine/ efavirenz) has also dropped considerably over the last two years (43% reduction) to US$ 243 per patient per year (3).

Similarly, the generic production, by Indian drug manufacturers, of imatinib, a crucial cancer drug essential in prolonging the life of patients suffering from chronic myeloid leukaemia (CML) played a crucial role in significantly increasing the access of cancer patients to this drug. The drug is considered to be the first line of treatment for CML, fights cancer cells without being toxic to healthy cells, and has to be taken lifelong. In addition, it is now being tested for treating other forms of cancer. The generic version of imatinib is priced at less than one tenth of the price of the originator at approximately Rs 8,000 per patient per month, compared to Novartis' price of approximately Rs 1,20,000 per patient per month.

That is because, until recently, India did not grant patents on medicines (4), which allowed Indian generic manufacturers to compete with multinational pharmaceutical companies and with each other to produce lower-priced generic versions of drugs patented in other countries. This sort of generic competition among multiple producers is what made the cost of AIDS medicines fall dramatically and helped facilitate the scale-up of antiretroviral therapy to millions living with HIV in the developing world.

Patents in India threaten a key source of affordable medicines

However, India is drying up as a source of affordable versions of newer and future medicines. This is due to amendments made to India's patent law in 2005 (5), when the country was required to begin reviewing pharmaceutical product patents according to its international obligations under the World Trade Organization (WTO) Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS).

Patenting of medicines in India could mean that Indian manufacturers will no longer be able to produce cheaper versions of newer medicines. Precisely such newer drugs are crucial, for example, for the treatment of HIV/AIDS, hepatitis C, cancer and other diseases.

Fortunately, when the Indian Parliament amended its patent law in 2005, an effort was made to find a balance between the intellectual property rights of pharmaceutical companies and the need to protect public health, ensure supply to national treatment programmes and make drugs as affordable as possible.

While section 3(d) of the amended Indian Patent Act, 2005, was inserted to safeguard against the granting of frivolous patents on trivial improvements of known molecules, there was also a great concern about those new drugs (new chemical entities) invented after 1995 that would be patented under Indian law. To this end, key safeguards in India's amended patent law such as the "early working exception" (section 107 A) and the provisions on compulsory licensing (sections 84, 92, 92A and 100) were also included in the law to ensure generic production in the event that patent holders failed to fulfill their duty to make patented medicines available and affordable to patients.

Now both the early working exception and compulsory licensing provisions that create mechanisms for generic competition are at considerable risk because of a pending court case filed by Bayer against the Union of India and the Drugs Controller General of India (DCGI).

The Bayer case against the Union of India

After the 2005 amendment of the Indian patent law, multinational pharmaceutical companies have been pushing India's drug regulator, the DCGI, to implement patent linkage in India.

Establishing a link between patent status on the one hand and the registration (also known as marketing approval) of a medicine on the other hand means that a national drug regulatory authority is required to withhold marketing approval to a generic version of a patented drug, regardless of whether the patent granted is valid or not.

A petition was filed by Bayer in 2008, seeking to stop the DCGI from granting marketing approval to a generic version of a patented cancer drug. The case was filed before the Delhi High Court on the grounds that the DCGI had entertained the application for granting marketing approval to a generic version of the anti-cancer drug sorafenib tosylate, for which Bayer has obtained a patent (IN215758) in India. (Sorafenib is a drug approved for the treatment of renal and liver cancer.)

By filing this case against the Indian government, Bayer seeks to ensure that Indian drug regulatory authorities do not register a cheaper generic version of a drug, if it is patented.

All medicines to be sold in the Indian market require prior marketing approval from the DCGI. If Bayer's demands in its case against the government of India are accepted, it will block the marketing approval of generic versions of patented medicines – even if the patent is wrongly granted or the approval is with the objective of applying for a compulsory license or entering the market once the patent has expired.

But a drug regulatory authority's role is to ensure that medicines marketed in a country are proved to be of quality, safe and effective: it delivers a necessary green light before a drug can be manufactured or marketed. Its role is not to deal with the patent status of the medicines, which is the role of a country's patent office.

Chronology of the Bayer case

The petition was first heard by a single judge bench of the Delhi High Court in 2009 and was dismissed as "vexatious and luxury litigation". Justice Ravindra Bhat rejected Bayer's petition seeking to prevent the DCGI from registering Cipla's version of sorafenib and made it clear that "Bayer's argument of inferring drug agencies' role in patent policing or enforcement is unacceptable."(6)

Bayer filed an appeal against the decision before the Division Bench of the Delhi High Court.

In a welcome move for access to medicines, this decision was upheld by the Division Bench in February 2010. In the words of the judges of the Division Bench,

> This Court concurs with the learned Single Judge that the scheme of both the Patents Act and the Drugs & Cosmetic Act are distinct and separate and that the attempt by the appellant Bayer to establish a linkage cannot be countenanced. If Bayer's argument were to be accepted, it would mean that instead of the validity of the patent being tested, if at all, either in revocation proceedings or by way of a counter-claim in infringement proceedings instituted by the patent holder, the DCGI will begin with the presumption that the patent granted in respect of the drug for which marketing approval is sought has been validly granted. (7)

But Bayer has now dragged the Indian drug regulator and the Indian government to the Supreme Court. It has filed a special leave petition against the decision of the Delhi High Court in the Supreme Court which was admitted for hearing on February 26, 2010.

Implications of the Delhi High Court decision

The Court's decision was very important because it stopped Bayer's attempt to introduce a new barrier to generic competition and ensured that different public health safeguards in India's patents law remain useable.

One safeguard in the patent law, known as the "Bolar" or "early working exception", allows a generic producer to manufacture a drug even when it is under patent and obtain marketing authorisation in advance, so that a generic can be put on the market as soon as the patent is invalidated or revoked, or expires. India's patent law allows manufacturers to do this without fear of facing an infringement suit.

A second safeguard is compulsory licensing. Compulsory licenses can be issued to generic producers if patented essential medicines are not available or affordable in India, or if other countries which lack production capacity order essential drugs

from India. But if Bayer had succeeded in introducing patent linkage in India, this could have blocked the marketing approval of generic medicines made under the terms of a compulsory license, thereby rendering the compulsory license useless.

These public health safeguards will become increasingly important as the effect of the newly introduced pharmaceutical product patent regime is felt in the country. The TRIPS Agreement made it mandatory for India to have a patent regime for medicines by 2005.

Five years after India revised its 1970 Patents Act, patent offices have granted product patents on several drugs, including medicines for HIV/AIDS, hepatitis C and cancer. The patented drugs are prohibitively expensive and in the absence of generic competitors will remain out of reach of patients.

On March 3, 2006, Roche proudly announced it was "becoming the first pharmaceutical company in India to receive a product patent under the new patent regime". The patent granted is on peginterferon alfa-2a, a new generation hepatitis C therapy. The cost of this therapy is prohibitively high – above Rs 12,000 for a single dose vial of 180 mg.

Patent linkage in other countries

Efforts to link registration (marketing approval) of drugs with their patent status are not new and have been pushed by the multinational pharmaceutical industry, its associations, and the United States. Several developing countries have been under pressure to introduce patent linkages. Chile, Morocco and Bahrain were made to accept TRIPS-plus provisions, including patent linkages, in the Free Trade Agreements that they signed with the US.

In 2006, Pfizer filed a case in the Philippines against the drug regulators (Bureau of Food and Drugs or BFAD) and a government-owned pharmaceutical company (PITC, Philippine International Trading Corporation) to prevent them from registering a generic version of a patented medicine. PITC had started the process of registering the generic version of amlodipine besylate with the BFAD by submitting samples imported from India so that it could obtain marketing approval (registration) and then promptly enter the market when Pfizer's Philippines patent on amlodipine besylate expired in June 2007. The drug is used to treat high blood pressure and is considerably cheaper (5 times) in India because of generic competition.

Subsequent to the above mentioned court case, the Philippines government eliminated patent linkage and intellectual property protection from the responsibilities of BFAD under a department of health administrative order, AO No 2005-0001. The order permits BFAD to consider and process applications for marketing approval of generic versions of medicines without the need to verify whether or not the pharmaceutical being submitted for registration is under patent (8).

The European Union does not implement patent linkage. The EU Directorate General for Competition has noted that "patent-linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No 2001/83" and has documented the widespread use of litigation (including that against drug regulators) in attempts to enforce patent linkages, much like Bayer's case in India (9). It is interesting that Bayer, a European company, is in court in India attempting to get rights that it does not even enjoy in Europe.

In the US, which has a patent linkage system, the use of the system by patent holders to delay generic entry has been recorded in detail by the US Federal Trade Commission (10). In addition, its Food and Drug Administration has officially stated that its resources would be better utilised in reviewing applications than in reviewing patent claims, in addition to the fact that it does not have the expertise to review patent information (11).

How companies use patent linkage to block generics: the case of fluconazole in Africa

Medecins Sans Frontieres (MSF) has documented a typical case of how patent linkage can affect access to medicines. An Indian generic manufacturer was refused marketing approval by the drug regulator in an African country for its generic version of fluconazole, a drug used to treat opportunistic infections associated with HIV. On investigation, MSF learnt that the grounds for this refusal was that the drug regulator had been informed by the originator pharmaceutical company that it had a patent on the drug in the country. The drug regulator had no legal obligation to refuse registration on such grounds, but it had been pressured to do so by the pharmaceutical company. Under further investigation, it was revealed that the originator pharmaceutical company's claim was false and that the patent had expired more than a year earlier. The drug regulator eventually retracted its decision, and allowed the registration of the Indian company's low-cost generic version of the drug (12).

World Health Organization's advice on the issue

In March 2006, the World Health Organization issued a briefing note on "access to medicines" in which it discussed the impact of TRIPS-plus provisions. This note states that patent linkages are problematic as drug regulators are likely not to possess the resources or manpower to check the patent status of medicines. Moreover they would lack the necessary expertise to assess whether a patent is valid or would be infringed and would thus be more likely to enforce all patents including invalid ones.

The Cancer Patients Aid Association intervenes to protect patients' interests

By filing this case against the Indian government, Bayer wants to set a legal precedent which will require the DCGI to block regulatory approval of affordable versions of patented medicines – even if the generic has been proved to be of quality, safe and effective. As discussed above, this will seriously undermine the use of provisions in Indian law that ensure that even patented medicines are available and affordable in India and other developing countries.

The Cancer Patients Aid Association had filed an intervention application in Bayer's case against the government of India in the Delhi High Court. It intends to continue defending patients' interests in the Supreme Court of India. At stake are patients' lives across the developing world.

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